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MAIL STOP RCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of:
Lisbeth Illum, *et al.*

Conf. No.: 2569

: Group Art Unit: 1615

Appln. No.: 09/834,312

: Examiner: Blessing M. Fubara

Filing Date: April 13, 2001

: Attorney Docket No.: 10774-56US
(WESX/P21598US)

Title: NOVEL FORMULATIONS OF FEXOFENADINE

REQUEST FOR RECONSIDERATION

This is in further response to the Office Action dated July 15, 2004 (Paper No. 20040628) and in response to the Advisory Action dated November 18, 2004 (Paper No. 20041114). This request is being timely filed in view of a Petition for One Month Extension of Time from the date of the Advisory Action (as set in subparagraph (b) of the Advisory Action). The finality of the Office Action of July 15, 2004 is being withdrawn by the filing of the accompanying Request for Continued Examination (RCE).

Claims 7, 20, 21 and 28-58 are presently pending in the application.

Based upon the entry of the Amendment After Final of October 14, 2004, as requested in the accompanying RCE Request, the Examiner has withdrawn the rejection under 35 U.S.C. § 112 and the prior art rejections over Aslanian and Hwang (see page 2 of the Advisory Action). Accordingly, it is Applicants' understanding that the only remaining rejections pending in the application are as follows:

(a) the rejection of claims 40 and 49 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,254,129 of Carr et al. (paragraph 4 of the final Office Action);

(b) the rejection of claims 41-43 under 35 U.S.C. § 103(a) as being unpatentable over Carr et al. (paragraph 17 of the final Office Action);

(c) the rejection of claims 35-37, 30-33, 41, 46, 52-54 and 58 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0111495 of Magee et al. (see paragraph 18 of the final Office Action); and

(d) the rejection of claims 34, 7, 20, 21, 28, 29, 38, 39, 40, 44, 45 and 47-51 under 35 U.S.C. § 103(a) as being unpatentable over Carr et al. in combination with Magee et al. (see paragraph 19 of the final Office Action).

These rejections are respectfully but strenuously traversed for the reasons set forth in the Remarks section of the Amendment filed October 14, 2004, which are incorporated herein by reference, and the following additional Remarks which respond more specifically to the Examiner's comments at page 2 of the Advisory Action.

In the Advisory Action, the Examiner states that the art rejection over Carr is maintained. Applicants assume that the Examiner means all of the rejections listed above which are based in whole or in part on Carr et al. ("Carr"). The Examiner finds unpersuasive Applicants' argument that Carr does not disclose pharmaceutical excipients that increase the solubility of fexofenadine, because Carr allegedly discloses the claimed excipients with fexofenadine, and Applicants have not provided any data to show that Applicants' excipients would not also increase solubility in the prior art. The Examiner argues that the prior art does not have to expressly state that the claimed excipients would increase the solubility of fexofenadine, since the properties of a composition cannot be separated from the composition itself.

Applicants agree in principle that the properties of a composition cannot be separated from the composition itself, and that the prior art does not have to expressly disclose the properties of the composition. However, the Examiner's argument in the Advisory Action is not understood insofar as the Examiner contends that "Carr discloses the claimed excipients with the fexofenadine." Thus, the Examiner has already conceded in paragraph 3 of the final Office Action that "the fexofenadine composition of Carr does not contain cyclodextrin or glycofurol."

All of the claims which the Examiner has rejected over Carr, either alone or in combination, require the presence of cyclodextrin and/or glycofurol. Thus, each of the

independent claims rejected over Carr, namely claims 35, 40 and 41, requires in clause (ii) a pharmaceutical excipient selected from the group consisting of a cyclodextrin and glycofurol. All of the remaining claims rejected over Carr depend directly or indirectly from one of these independent claims 35, 40 or 41, and therefore contain the same clause and the same requirement. It is noted that claim 34 contains exactly the same clause (ii) and that the Examiner withdrew the rejection of claim 34 because the fexofenadine composition of Carr does not contain cyclodextrin or glycofurol.

Therefore, the rejection of independent claims 35, 40 and 41 and the claims depending therefrom should be withdrawn for the same reason. Reconsideration and withdrawal of these rejections are respectfully solicited. In the event that the Examiner maintains any rejection based upon Carr, the Examiner is required to explain explicitly where Carr teaches the use of cyclodextrin or glycofurol.

With respect to the published Magee et al. application ("Magee"), the Examiner rejects Applicants' argument that Magee cannot be prior art because the effective filing date of the published Magee application cannot be the filing dates of the priority provisional applications. Instead, the Examiner argues that the effective U.S. filing dates of Magee are the filing dates of the priority documents. This position of the Examiner is also respectfully but strenuously traversed.

Applicants concede that Magee discloses on the face of the patent application publication three related U.S. provisional patent applications, two of which were filed in 1997 and 1998. However, Magee does not and cannot claim priority from those two applications. Thus, by the very terms of the provisional application statute (35 U.S.C. § 111(b)), a provisional application automatically becomes abandoned one year from the provisional application filing date. Therefore, the provisional applications filed in 1997 and 1998 by Magee automatically expired on April 4, 1998 and October 21, 1999. Since the cited Magee publication was not filed until January 31, 2002, no priority can be claimed from these provisional applications.

At most, Magee could claim priority from the third listed provisional application filed on January 31, 2001. However, even assuming that that Provisional Application No. 60/265,240 contains support for the disclosure in the publication relied upon by the Examiner, the January 31, 2001 filing date is too late to qualify as prior art against the present application, which claims

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priority to a UK patent application filed October 13, 1998, through a PCT application filed October 12, 1999.

Applicants note that Magee also references a number of other co-pending applications which claim priority from the 1997 and 1998 provisional applications. Thus, in paragraph [0001] at page 1 of the Magee publication, Magee references a PCT application claiming priority from Provisional Application No. 60/043,403, filed April 4, 1997, and in paragraph [0002], Magee references a co-pending non-provisional application claiming priority from Provisional Application No. 60/105,120, filed October 21, 1998. However, again, it is noted that Magee does not claim priority from the PCT application or the non-provisional application disclosed in paragraphs [0001] or [0002]. Therefore, even if there were support in the provisional applications for the disclosure in the Magee published patent application relied upon by the Examiner, the Magee reference is not entitled to the filing date of the provisional applications, because, on the face of the Magee publication, Magee does not claim priority from the intermediate PCT or non-provisional applications.

Moreover, even if Magee were to subsequently claim priority from these applications, it does not appear that Magee could establish continuity of disclosed subject matter for the disclosure upon which the Examiner relies. Thus, in paragraph [0001] of Magee, Magee states that nothing disclosed in the above applications would teach a person skilled in the art "the novel compounds of the present invention or their unexpectedly high level of inhibitory selectivity for PDE4 isozymes." Similarly, in paragraph [0002] of the published application, Magee states that "the disclosed compounds and processes are not the same as those of the present invention." Therefore, it does not appear that the continuity of disclosure could be established through the series of Magee applications in order to give Magee an effective filing date of April 4, 1997, so as to qualify as § 102(e) prior art against the present application.

In view of the above, it appears that, at best, Magee has an effective filing date of January 31, 2001, which is not sufficient to qualify as prior art against the present application, which is entitled to a filing date of October 13, 1998. Therefore, the prior art rejections based in whole or in part on Magee are improper, and reconsideration and withdrawal of the rejections are respectfully requested.

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In the event that the Examiner maintains any rejections based upon Magee, the Examiner is required to establish the entitlement of Magee to the April 4, 1997 filing date, not only by establishing continuity of disclosure from the first provisional application through the published patent application, but also that Magee in fact claimed priority through all of these applications. Otherwise, any rejection based upon Magee must be withdrawn.

In view of the above Remarks, it is submitted that all of the claims in the application patentably distinguish over the prior art and are in condition for allowance. Reconsideration and an early Notice of Allowance are therefore respectfully solicited.

CORRESPONDENCE ADDRESS

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December 14, 2004
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